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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/506,011	02/17/2000	John Cooper Cox	017227/0155	6856

22428 7590 10/18/2006

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EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 10/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/506,011	COX ET AL.	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,6-8,12-17 and 53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,6-8,12-17 and 53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 2, 4-5, 9-11 and 18-52 are cancelled. Claims 1, 3, 6-8, 12-17 and 53 are pending and under examination.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3, 6 and 12-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Garcon et al.[1]

In response to the rejection, Applicant submits that Garcon et al. does not teach the claims as amended. Applicant submits that Garcon et al. neither teaches nor suggests an interaction, and the specification draws a clear distinction between electrostatic interaction and other forms of association, such as entrapment.

Applicant's submission has been considered, however, it not found persuasive. In the instant, the composition of Garcon et al. comprises a negatively charged organic complex and a positively charged antigen. The organic complex of Garcon et al. comprises saponin and sterol. Thus, the composition of Garcon et al. is the same as the claimed composition. The only deficiency noted in the teachings of Garcon et al. is that Garcon et al. fails to identify or note that the negatively charged organic complex

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[1] Garcon et al. WO 96/33739, published 10/31/1996

and a positively charged antigen are associated by an electrostatic interaction. However, this deficiency or silence does not render the claimed invention patentable. The composition of Garcon et al. comprises negatively charged organic complex and a positively charged antigen. General chemistry alone can assure that the charges will attract one another. Thus, while the electrostatic interaction between the negatively charged organic complex and a positively charged antigen are not stated by Garcon et al., the electrostatic interaction between the two charges are inherently present in the composition of Garcon et al. As stated, based on the general principles of chemistry, the two charges are attracted to one another to form the necessary electrostatic interaction. In the instant, Applicant is reminded that Garcon et al. does not need expressly teach that the negatively charged organic complex and a positively charged antigen are associated by electrostatic interaction to anticipate the claimed invention.

4. Claims 1, 3, 7, 12-13 and 17are rejected under 35 U.S.C. 102(b) as being anticipated by MacFarlan et al.[2]

In response to the rejection, Applicant submits that MacFarlan et al. teaches an immunostimulatory complex matrix comprising a saponin preparation, a sterol, a phospholipid and a metal chelating moiety capable of binding a polypeptide having at least one chelating amino acid sequence in the presence of metal ions; that is uncharged.

Applicant's submission has been considered, however, it is not found persuasive. In addition to teaching an immunostimulatory complex matrix comprising a saponin

[2] MacFarlan et al. WO 98/36772, published 08/27/1998.

preparation, a sterol, a phospholipid and a metal chelating moiety capable of binding a polypeptide having at least one chelating amino acid sequence in the presence of metal ions; MacFarlan et al. also teaches an immunostimulatory complex matrix comprising a saponin preparation, a sterol and phospholipid. The immunostimulatory complex matrix of MacFarlan et al. is Applicant's negatively charged organic complex. MacFarlan et al. then mixed this negative charged organic complex with a positively charged antigen. Hence, the mixing of negative charged organic complex with a positively charged antigen renders a composition comprising negative charged organic complex and a positively charged antigen that are associated by electrostatic interaction.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 6, 8 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over MacFarlan et al. as applied to claims 1 and 3 above, and further in view of Garcon et al.

In response to the rejection, Applicant submits that neither Garcon et al. nor MacFarlan et al. teaches the claimed composition for reason(s) cited in paragraphs 4 and 5 of this office action.

All of Applicant's submission has been considered, however, it is not found persuasive for the reason(s) set forth in the paragraphs following paragraphs 4 and 5 of this office action. Hence, the rejection is maintained.

Double Patenting

7. In response to the rejection, Applicant submits that Applicant intend to continue deference any argument or "corrective" action concerning the rejection until allowable subject matter is arrived upon.

Applicant's submission has been considered. Until the rejection is properly addressed, the rejection is maintained.

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1, 3, 6-8, 12-17 and 53 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 46-55, 63-64, 67-76 and 85 of copending Application No. 10/622470, for reason(s) of record. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

In response to the double patenting rejection set forth in the previous office action, Applicant submits the intention to defer any argument or corrective action concerning the rejection.

Applicant's intention is noted. However, until the rejection is properly addressed, the rejection is maintained.

Conclusion

10. No claims are allowed.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Primary Patent Examiner
Art Unit 1648

E.Le